

REMARKS

As originally filed, the application included claims 1-43. Claims 1, 10, 19, 23, and 37 are in independent form. By this paper, claims 18 and 39 have been amended. No claims have been cancelled. Accordingly, claims 1-43 remain in the application.

As a preliminary matter, election has been required between a first species of FIG. 3 and a second species of FIG. 6. Currently, claims 1, 10, 19, 23, and 37 are generic.

✓ During a telephone conversation with the Examiner on March 4, 2003, the undersigned provisionally elected the claims corresponding to species 1 (FIG. 3), namely, claims 1, 2, 4-11, 13-20, 22-30, 32-41, and 43. This election is hereby affirmed.

Claims 3, 12, 21, 31, and 42 of species 2 (FIG. 6) are withdrawn from further consideration. However, upon allowance of their corresponding independent claims, it is respectfully requested that allowance of the non-elected claims be further considered. Accordingly, the non-elected claims have not been cancelled.

Claims 23-30 and 32-36 are allowed. Claims 38-41 and claim 43 are indicated as being allowable if rewritten to overcome the rejection under 37 U.S.C. § 1.12, second paragraph, as will be discussed subsequently. Acknowledgement of allowable subject matter is greatly appreciated.

The specification is objected to because it is considered to be unclear, from pages 11-12 of the specification, how the method of effecting mitral valve annulus geometry can include the step of fixing a cable to the first anchor after fixing first and second anchors within the heart and how the first anchor is provided with a cable extending proximally therefrom after deploying the first anchor to the coronary sinus. The Examiner notes that it appears from pages 11-12 that the cable is already fixed to the first anchor prior to fixing of the first anchor.

Correspondingly, claims 19, 20, 22, 37-41, and 43 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Claims 19 and 37 are considered indefinite on the grounds that it is unclear from the specification how the method of effecting mitral valve annulus geometry can include the step of fixing a cable to the first anchor after fixing first and second anchors within the heart and how the first anchor is provided with a cable extending proximally therefrom after deploying the first anchor in the coronary sinus.

Firstly, it is agreed that pages 11-12 of the specification clearly teach that the cable is already fixed to the first anchor prior to the first anchor being deployed in the coronary sinus. It is well established law that a method claim is not limited to the order in which the method steps are presented in the claim unless the claim specifically limits the performance of the method steps to a particular order. The order of the steps in the independent method claims 23 and 37 was purposely chosen to make it expressly clear that the method claims were not intended to be interpreted so as to be limited to the fixation of the cable to the first anchor prior to the first anchor being deployed within the coronary sinus. Paragraphs 19 and 21 summarize the invention as defined in the claims. As a result, paragraphs 19 and 21 are consistent with the recitations of independent method claims 19 and 37.

From the above, it is respectfully submitted that claims 19 and 37 are in proper form in compliance with 35 U.S.C. § 112, that the Summary of the Invention provides a summary consistent with the proper extendable interpretation of method claims 19 and 37, and that the disclosure in the specification including pages 11-12, is to one embodiment of the present invention covered by method claims 19 and 37. Accordingly, it is respectfully requested that the objection to the specification and the 35 U.S.C. § 112, second paragraph, rejection of claim 19, 20, 22, 37-41, and 43 be withdrawn.

Claims 18 and 39 stand objected to because of noted alleged informalities. The Examiner has helpfully suggested amendments to these claims to overcome these objections. It will be noted that all of the suggested amendments to claims 18 and 39 have been made by this paper except the suggestion for the insertion of the article --a- - after "includes" in claim 18. This amendment has not been incorporated because "means" may be properly interpreted as being singular or plural. Hence, the term "coupling means" may also be properly interpreted as being singular or plural. Hence, in order to be consistent with an interpretation of "coupling means" as being plural, the article --a- - has not been inserted after "includes". Accordingly, it is respectfully submitted that the objections to claims 18 and 39 have been overcome.

With respect to the prior art, claims 1, 2, 4-11, 13-20, and 22 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Solem, et al., (U.S. PAP 2001/0018611), published August 30, 2001, in view of Lashinski, et al. (U.S. PAP 2002/0151961), published October 17, 2002. It is alleged that Solem, et al. discloses a device and method

with all of the elements or steps defined in claims 1, 10, and 19. However, it is properly recognized that Solem, et al. fails to describe a lock that locks the cable on the second anchor. Lashinski, et al. is cited as including a ratchet lock.

The 35 U.S.C. § 103(a) rejection of claims 1, 2, 4-11, 13-20, and 22 is respectfully traversed. It is respectfully submitted that the combination of Solem, et al. and Lashinski, et al. fails to show, describe, or even suggest the invention as defined by the rejected claims. For the reasons set forth hereinafter, reconsideration and allowance of claims 1, 2, 4-11, 13-20, and 22 are respectfully requested.

Applicants have invented a new and improved device for effecting mitral valve annulus geometry of a heart and method. The device, as defined in claim 1, includes a first anchor configured to be positioned within and fixed to the coronary sinus of the heart adjacent the mitral valve annulus within the heart and a cable fixed to the first anchor and extending proximally from the first anchor within the heart. Claim 1 further defines the device as including a second anchor configured to be positioned in and fixed in the heart proximal to the first anchor and arranged to slidably receive the cable and a lock that locks the cable on the second anchor. As further recited in claim 1, when the first and second anchors are fixed within the heart, the cable is drawn proximally, and the cable is locked on the second anchor, the geometry of the mitral valve is effected.

Claim 10 defines the device in terms of means plus function. Claim 19 defines a method of deploying the device.

It is respectfully submitted that claims 1, 10, and 19 are allowable over the combination of Solem, et al. and Lashinski, et al.. These claims are allowable over the combination of the cited references because even if the references were combined as suggested by the Examiner, a device and method as defined in claims 1, 10, and 19 would not result. Further, there is no suggestion in either Solem, et al. or Lashinski, et al. of their combination or of the desirability of their combination.

With respect to Solem, et al., the Examiner makes specific reference to FIGS. 12 and 13. The structure described in FIGS. 12 and 13 of Solem, et al. includes three stents, stent 23, stent 24, and stent 25, which are deployed in the coronary sinus. A pair of wires 26 and 27 may be pulled from outside the patient to adjust the distance between stent 23 and stent 24, and stent 24 and stent 25. More specifically, as illustrated in FIG. 12, wire 26 is connected to stent 24 and wire 27 is connected to stent 23. Hence, wire 27 may be

used to adjust the distance between stent 23 and stent 24. Wire 26 may be used to adjust the distance between stent 24 and stent 25.

The description in Solem, et al. with respect to FIGS. 12 and 13 is absolutely silent as to how the relative positions of the stents 23, 24, and 25 are maintained once their relative distances have been adjusted. Paragraph 54 of the published application is the paragraph which describes FIGS. 12 and 13. Nowhere in paragraph 54 is the term "lock" utilized in describing structure to maintain the relative distances between the stents, nor, is any equivalent description provided to that end.

Solem, et al. does, with respect to other embodiments, shows an arrangement for allegedly maintaining the distance between a pair of stents. However, the locking arrangement is intermediate the stents and not carried by any one of the stents.

Lashinski, et al. is cited as showing a device having a ratchet lock. The Examiner has specifically referenced FIGS. 17B and 17C of Lashinski. The device there shown includes a forming element 365 having a tensioning member 367 therein. At the distal end of the forming element is a ratchet assembly 367 which permits the tensioning member 365 to be engaged by a pawl 238. As the tension member 365 is pulled relative to the forming member 365, the forming member 365 will change in arcuate configuration as is illustrated in FIG. 17C.

The device of FIG. 17C lacks the first and second anchors as defined in claims 1, 10, and 19. Also, while Solem, et al. does show and describe stents which may be fixed in the coronary sinus, it is not seen how the wires of Solem may be modified to form a ratchet and pawl assembly as described in Lashinski. Further, since Solem, et al. does not include any suggestion that one of the stents may be provided with a lock, such as a ratchet mechanism, and since Lashinski fails to describe the first and second anchors as defined in claims 1, 10, and 19, it is respectfully submitted that neither Solem, et al. nor Lashinski, et al. contains any suggestion of their combination or any suggestion as to the desirability of their combination.

It is respectfully submitted that claims 1, 10, and 19 are clearly allowable over the 35 U.S. § 103(a) rejection based on Solem, et al. and Lashinski, et al. Neither reference shows, describes, or suggests a cable fixed to a first anchor, extending proximally from the first anchor and slidably received by a second anchor, and a lock that locks the cable on the second anchor. It is respectfully submitted that Solem, et al. and Lashinski, et al. fail to

show, describe, or suggest such structure and function. Further, in view of the foregoing, it is respectfully submitted that Solem and Lashinski fail to show, describe, or suggest the method as recited in claim 19. Hence, it is respectfully submitted that claims 1, 10, and 19 are clearly allowable over the 35 U.S.C. § 103(a) rejection based upon Solem, et al. and Lashinski, et al. Allowance of these claims is respectfully requested.

Since claims 2 and 4-9 are dependent from claim 1, claims 11 and 13-18 are dependent on claim 10, and claims 20 and 22 are dependent from claim 19, each adding further limitations to its corresponding independent claim, these claims are likewise considered to be allowable. Favorable reconsideration of these claims is also respectfully requested.

As it has been demonstrated that generic claims 1, 10, and 19 are allowable, it is respectfully requested that the non-elected claims 3, 12, and 21 be indicated as allowable as well. Further, since generic claim 23 has already been allowed, it is respectfully submitted that non-elected claim 31 should also be indicated as allowable.

Lastly, applicants wish to draw the Examiner's attention to Cohn, et al. (U.S. PAP 2002/0183841), published on December 5, 2002. While this publication is not considered to render any of the claims of the instant application non-allowable, it is considered to be illustrative of another device which may be utilized in the coronary sinus for effecting the mitral valve annulus. The device of Cohn, et al., as may best be seen in FIG. 9, includes a distal anchor 139 which engages an external surface of the heart, a proximal anchor 142 which engages the coronary sinus ostium, and a flexible body 124 extending from the distal anchor to the proximal anchor. The proximal anchor includes a ratchet.

As may be noted in FIG. 9 of Cohn, et al., the Cohn, et al. device does not include a first anchor configured to be positioned within and fixed to the coronary sinus of the heart. This structural difference between the Cohn, et al., device and the device of the present invention is exceedingly important because to deploy the Cohn, et al. device it is necessary to pierce through from the coronary sinus to external to the heart in order to deploy the distal anchor 139. This of course can lead to serious complications. Correspondingly, the method of deploying the Cohn, et al. device is substantially different than the method defined in the method claims of the instant application.

In view of the foregoing, it is respectfully submitted that all of the claims of the instant application are allowable over Cohn, et al. Hence, Cohn, et al. is being cited herein

to illustrate another device, other than that defined in the instant claims, which may be used in the coronary sinus of the heart.

With this amendment, the application is considered to be in condition for allowance. Favorable reconsideration and allowance of all rejected claims are respectfully solicited.

In the event additional fees are due as a result of this amendment, payment for those fees has been enclosed in the form of a check. Should further payment be required to cover such fees you are hereby authorized to charge such payment to Deposit Account No. 07-1897.

Respectfully submitted,

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A handwritten signature in black ink, appearing to read "Richard O. Gray, Jr.", with a stylized flourish at the end.

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